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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,784	01/22/2004	Winthrop D. Childers	200314403-1	6122

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
01/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/762,784	CHILDERS ET AL.	
	Examiner	Art Unit	
	JACQUELINE DIRAMIO	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-14, 16-18, 20 and 21* is/are pending in the application.

4a) Of the above claim(s) *11-14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2009 has been entered.

Status of the Claims

2. Applicant's amendments to claims 1, 11, 18 and 21 are acknowledged.

3. Currently, claims 1, 7 – 14, 16 – 18, 20 and 21 are pending. Claims 1, 7 – 10, 18, 20 and 21 are under examination. Claims 11 - 14, 16 and 17 are acknowledged as withdrawn as drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim 1, 7, 18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Burke et al. (US 2008/0098802) and Ward (US 5,410,504).

Groll teaches a self-calibrating disposable blood test strip (device) insertable in a meter, the test strip comprising:

a substrate configured for carrying a chemical reagent; and

circuitry formed on the substrate, the circuitry comprising:

a measurement (sensor) portion, i.e. measurement contact pads, associated with the chemical reagent to enable measurement of at least one of a presence and a concentration of a blood analyte;

an information storage portion, i.e. information contact pads, configured to store information indicative of at least one calibration value of the chemical reagent for calibrating operation of a meter to accurately measure and monitor a test of the blood analyte; and

an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the at least one calibration value from the information storage portion;

wherein the information storage portion is electrically connected to a portion of the measurement portion of the circuitry and includes at least one electrically conductive element including a plurality of electrically conductive contact pads (elements) each contact pad being configured to be physically altered by severing the conductive path (i.e. shorting via a fusible link) and a number, N, of the contact pads in a determinable order producing a characteristic measurement, such as resistance or conductivity, that is indicative of the at least one calibration value of the chemical reagent, the N contact pads producing 2^N different possible calibration values (see Figures 1-4 and 10-15; and paragraphs [0010], [0011], [0014], [0035], [0036], [0038], [0039], [0041], [0042], [0047], [0061], [0064]-[0070], [0075]-[0084], and [0094]).

Although Groll teaches that the characteristic measurement of the contact pads can comprise resistance or conductivity (see paragraph [0042]), Groll fails to teach that the characteristic measurement can also be impedance. Secondly, Groll teaches that the potential conductive links can be sensed or induced via "capacitive means" (see paragraph [0042]), however, Groll fails to specifically teach that the electrically conductive elements of the information storage portion are either a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel.

Burke et al. teach a system and method for accurately measuring an analyte in a fluid sample, wherein the system comprises a test strip with associated electrodes. The application of a fluid sample, i.e. blood, to the test strip results in sample covering the test electrodes, which results in the increase of the current response of the test electrodes because the sample is reacting with a reagent present on the test electrodes. The response current will reach a stable state, which indicates the impedance of the sample. The stable state response could also be measured

as current or voltage and the impedance can be calculated therefrom. In addition, one skilled in the art would recognize that measurements of impedance, resistance, current, conductivity or charge are interchangeable, wherein it is only necessary to adjust the measurement and correction mathematics to account for which measure is being employed (see Abstract; and paragraphs [0059] and [0061]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll the characteristic measurement of the electrically conductive elements (i.e. contact pads) comprising impedance as taught by Burke et al. because Burke et al. teach that a system comprising a test strip with associated electrodes, i.e. electrically conductive elements, can accurately measure an analyte in a fluid sample by monitoring the impedance of the test electrodes as the electrodes react with a fluid sample of interest. In addition, it would have been obvious matter of design choice to measure various electrical properties of the contact pads of Groll as taught by Burke et al. because Burke et al. teach that one skilled in the art would recognize that measurements of impedance, resistance, current, conductivity, or charge are interchangeable, wherein it is only necessary to adjust the measurement and correction mathematics in order to account for which measure is being employed.

Ward teaches a method of constructing a memory on a semiconductor substrate from a plurality of capacitor elements organized in a plurality of rows and columns, i.e. in parallel. The capacitor array may be used for storing information, such as a ROM. Each capacitor is used to store one bit of information, wherein a capacitor storing a "1" will have a different capacitance

than a capacitor storing a "0" (see Abstract; column 1, lines 63-68; column 2, lines 1-68; and column 3, lines 1-30).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll an array of capacitors arranged in parallel as the electrically conductive elements as taught by Ward because Ward teaches the benefit of creating a parallel capacitor array on a semiconductor substrate in order to create a memory that can be used for storing information, such as a ROM, wherein each capacitor is used to store one bit of information. In addition, the array of parallel capacitors taught by Ward is merely creating the same encoded information by storing bits of information as either a "1" or "0" within each capacitor, which is the same encoded information created via the contact pads of Groll (see paragraphs [0077]-[0079] of Groll).

With respect to Applicant's claim 7, Groll teaches that the test device can comprise a set of test devices with the information storage portion of each test device storing substantially the same information (see paragraphs [0012], [0066] and [0070]).

With respect to Applicant's claim 18, the limitations of this claim are discussed above with respect to claim 1.

With respect to Applicant's claim 20, Groll teaches that the information storage portion is inseparable from the disposable test strip (see paragraph [0065]).

With respect to Applicant's claim 21, the limitations of this claim are discussed above with respect to claim 1.

5. Claims 8 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Burke et al. (US 2008/0098802) and Ward (US 5,410,504), as applied to claim 1 above, and further in view of Mandecki (US 2002/0006673).

The Groll, Burke et al. and Ward references, which were discussed in the 103(a) rejection above, fail to teach that the circuitry of the substrate of the device comprises a semiconductor portion and a non-volatile memory, wherein an electrical signal generator external to the device is configured to send an electrical signal to the non-volatile memory to cause storage of the information in the information storage portion.

Mandecki teaches transponders for use in methods of detecting biomolecules in a sample, wherein the transponders comprise a solid phase, a reagent or biomolecule binding element, and an index number or memory element that is electronically encoded on the transponder. The index number can be unique to each solid phase, and is retrievable by a scanner device at any time during an assay. The index number can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay. The memory element can be encoded by a user just before, during or after a biological material is deposited on the surface of the transponder. The memory element is encoded with data sent by electromagnetic waves from a remote scanner read/write device, wherein the scanner read/write device further receives the encoded data transmitted by the transponder (see Abstract; and paragraphs [0007], [0009], [0021], [0027], [0031] and [0032]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll, Burke et al. and Ward a memory

element, wherein an external signal generator, i.e. scanner read/write device, is configured to send an electrical signal to the memory element to cause storage of information, as taught by Mandecki because Mandecki teaches the benefit of including a memory element on a transponder or solid phase device for detecting biomolecules in a sample, wherein the memory element can be encoded by an external scanner read/write device, in order to allow for encoding of the memory element by a user just before, during or after a biological material is deposited on the surface of the transponder. This encoding of the memory element allows for information to be stored within the transponder device for later retrieval, wherein the information can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay.

Response to Arguments

6. Applicant's arguments filed December 2, 2009 have been fully considered but they are not persuasive. Applicant argues (see pages 8-9) that the primary reference of Groll (US 2005/0019953) fails to teach that the test device/strip, which is "insertable in a meter," **includes** "an information storage portion configured to store information indicative of at least one calibration value of the chemical reagent," and instead, it's the ROM key or test meter of Groll that includes the calibration information. However, this argument is not found persuasive.

To begin, the test strip device of the Groll reference includes all of the structural elements of Applicant's claimed device, except for the use of impedance elements, wherein the impedance elements comprise a plurality of impedance elements that are arranged in a particular

configuration. However, these missing elements were remedied by the Burke et al. and Ward references, which were combined with Groll in the 103(a) rejection. Therefore, given that this combination of Groll in view of Burke et al. and Ward teaches all of the structural elements required by Applicant's claimed blood test device, the combination is capable of performing the intended use recited by Applicant's claim of "storing information indicative of at least one calibration value of the chemical reagent."

Secondly, the Groll reference does teach the encoding of various information directly onto the test strip of Groll, wherein the test strip of Groll is insertable into a meter (see paragraphs [0061], and [0065]-[0074]). This information encoded onto the test strip of Groll would read upon the calibration information or values recited within Applicant's independent claim 1. Therefore, it is unclear why calibration information is not stored on the test strip itself, as argued by Applicant, but is only stored on the ROM key or test meter, given that Groll specifically teaches the encoding of various information on the test strip itself. It is further noted that the provided "ROM key" of Groll, which might be considered an "other source of calibration information," is not a necessary source of information required "for calibration of the meter." The "ROM" key is merely used for verifying that the calibration information encoded on the test strip device matches the calibration information included on the "ROM" key (see paragraphs [0061]-[0070]). This "ROM" key comprises a part of the intended use of the device of Groll. However, because the device of Groll, in combination with Burke et al. and Ward, includes all of the required structural elements of Applicant's claimed device, the device of Groll is capable of performing the intended use and again, meets the claim.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/GAILENE R. GABEL/
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1/16/2010